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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,280	12/21/2000	Michinobu Nakamura	197748US0PCT	5123

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EXAMINER
AFREMOVA, VERA

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/674,280	Applicant(s) Nakamura et al.
	Examiner Vera Afremova	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 21, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *7, 8, 14, 15, and 22-26* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *7, 8, 14, 15, and 22-26* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of claims

Claims 7, 8, 14, 15 and 22-26 as amended are pending and under examination. [Paper No. 21 filed 4/21/2003].

Claims 1-6 were canceled by applicants. [Paper No. 9 filed 10/29/2001].

Claims 9-13 and 16-21 were canceled by applicants [Paper No. 12 filed 5/14/2002].

Claim Rejections - 35 USC § 112

Claims 7, 8, 14, 15 and 22-26 as amended remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims remain indefinite with regard to limitation such as "completion" of the enzymatic reaction and/or degree of "completion" of the enzymatic reaction since it is uncertain as claimed and as disclosed what is an indication of completion as intended in order to determine the degree of completion as claimed. It is uncertain what is measured in order to evaluate the claimed degree of "completion".

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7, 8 and 22-26 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/28853 [N] in view of US 4,808,419 [D].

The claims are directed to a method for producing hydrolyzed protein from vegetable protein material wherein the method comprises step of preparing a fungal koji mold culture inoculum, step of mixing the fungal koji mold culture inoculum with a vegetable protein material, step of conducting enzymatic hydrolysis at first temperature of about 15-39°C or about 25-38°C with aeration and agitation and then at second temperature of about 40-60°C or of about 41-50°C . The claimed step of preparing a fungal koji mold culture inoculum is conducted in a "submerged culture fermenter-type reaction vessel". The final hydrolyzed protein contains 5% and less of reducing sugars. The temperature shift is conducted at the time of 10-60% completion of enzymatic hydrolysis. Some claims are further drawn to the use of vegetable protein material such as wheat gluten or de-fatted soybean.

WO 95/28853 [N] discloses a method for producing hydrolyzed protein or a seasoning sauce (see page 9, last paragraph) wherein the method comprises step of preparing a fungal koji mold culture comprising *Aspergillus oryzae*, step of mixing the fungal koji mold culture with a vegetable protein material such as pretreated wheat gluten, step of conducting enzymatic hydrolysis at first temperature of about 30 °C with aeration and agitation or mixing and then at second temperature of about 40-45°C. The method of the cited patent WO 95/28853 [N] encompasses the use of temperature shift within the ranges identical to the presently claimed method. The cited method encompasses the use of a container or a fermenter for liquid or submerged fermentation reaction or enzymatic hydrolysis by teaching the use of a liquefied gluten suspension within the container wherein it is further mixed with fungal koji mold culture

(page 9, par. 2, line 1, 3 and 14). The cited reference also suggests the use of defatted soybean as vegetable material (page 1, par. 1) in a method for producing hydrolyzed protein from vegetable material.

Although the cited patent WO 95/28853 [N] does not clearly disclose concentration of reducing sugars in the final hydrolyzed protein product, their amounts are considered to be substantially similar, if not identical, to the presently claimed amounts because the identical vegetable materials are subjected to identical two-temperature stage enzymatic hydrolysis by using identical koji mold fungal culture as presently claimed and as disclosed by the cited patent. Thus, the final products would be substantially similar, if not identical, as result of practicing substantially similar protocols of making. Moreover, the cited patent WO 95/28853 [N] clearly teaches making and obtaining a hydrolyzed protein product with a "lighter" color that is reasonably expected to be due to the lack of reducing sugars which commonly have browning effects (see instant specification page 5, par. 3).

Although the cited patent WO 95/28853 [N] does not clearly disclose degree of completion of enzymatic reaction at the moment of temperature switch, the same vegetable material is hydrolyzed at the same conditions as claimed, and, thus, the degree of completion is reasonably expected to be the same as in the claimed method, particularly in view that identical temperature ranges are used for producing hydrolyzed protein in the cited method and in the claimed method.

The cited patent WO 95/28853 [N] does not clearly discloses the design of container in the method for producing hydrolyzed protein.

However, the cited patent US 4,808,419 [D] is relied upon to demonstrate that fermenters for submerged or semi-solid fermentation of vegetable materials by microbial enzymatic hydrolysis including the use of koji preparation derived from *Aspergillus oryzae* are known in the art and commercially available (see abstract or Fig. 1 or col. 10, line 30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice the method of WO 95/28853 [N] in "a submerged culture fermenter-type reaction vessel" as intended the presently claimed invention with a reasonable expectation of success in producing hydrolyzed proteins with decreased amounts of reducing sugars because various fermenters including submerged culture fermenter-type reaction vessel are known in the prior art as demonstrated by US 4,808,419 [D], for example, and they are available for fermentation and hydrolysis of vegetable materials including koji fermentation. One of skill in the art is free to choose a fermenter suitable for koji fermentation which is known and/or available on a market. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims 7, 8 and 22-26 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,045,819 [A] in view of US 4,808,419 [D].

The claims are directed to a method for producing hydrolyzed protein from vegetable protein material wherein the method comprises step of preparing a fungal koji mold culture inoculum, step of mixing the fungal koji mold culture inoculum with a vegetable protein material, step of conducting enzymatic hydrolysis at first temperature of about 15-39°C or about 25-38°C with aeration and agitation and then at second temperature of about 40-60°C or of about 41-50°C . The claimed step of preparing a fungal koji mold culture is conducted in a "submerged culture fermenter-type reaction vessel". The final hydrolyzed protein contains 5% and less of reducing sugars. Some claims are further drawn to the use of vegetable protein material such as wheat gluten or de-fatted soybean.

US 6,045,819 [A] discloses a method for producing hydrolyzed protein from vegetable material wherein the method comprises step of preparing a koji starter or a fungal culture inoculum derived from various koji molds including *Aspergillus oryzae* (col. 10, lines 30-39 and col.11, lines 47-50), mixing the koji starter with a vegetable material such as de-fatted soybeans (col. 9, lines 55-57), step of conducting first stage fermentation at temperature 28-30°C with aeration (col.9, line 60) and conducting second stage fermentation at temperature 30-60°C (col. 10, line 66) or 50°C (col. 11, line 56) or 58 °C (col. 12, line 2). The cited method encompasses the use of a liquid or "submerged culture fermenter-type reaction vessel" by disclosing a device capable to hold fermentation reaction with addition of water into reaction system (col. 11, lines

66-68; col. 8, line 65) in a method for producing hydrolyzed protein. The final hydrolyzed product obtained by two stage temperature fermentation of the cited patent is substantially free from reducing sugars because the cited patent teaches that the glycosidic saccharide originally present in vegetable material are decomposed to an undetectable extend (col. 12, line 21 and line 31).

In addition, the cited patent US 6,045,819 [A] teaches pre-treatment of vegetable material before enzymatic hydrolysis. The method of the cited patent encompasses step of pulverization of vegetable material prior to fermentation by teaching the use of soy powder or small granules (see col. 9, lines 11-20, for example). The cited method teaches a step of pasteurization or sterilization of vegetable material prior to fermentation by teaching cooking and/or heating soybeans (Fig. 1). The cited method encompasses steps of removing air bubbles from vegetable material prior sterilization or cooking by teaching kneading vegetable material into blocks (col. 9, lines 22-23) or by teaching a cooking step which is reasonably expected to remove at least some air bubbles due to increase of temperature and evaporation. The cited method encompasses sequential steps of dispersing pulverized vegetable material in hot water, removing air bubbles and sterilizing by teaching cooking of vegetable material prior to enzymatic fermentation with koji mold fungal culture.

The method of the cited patent US 6,045,819 [A] is substantially similar the claimed method because it comprises identical steps drawn to the use of two temperature stage enzymatic hydrolysis of identical vegetable protein material with substantially identical fungal culture

which is a source of enzyme required for hydrolysis such as koji mold fungus *Aspergillus oryzae* wherein the method results in the possession of identical hydrolyzed protein product which is substantially free from reducing sugars.

The cited patent US 6,045,819 [A] is silent with regard to a particular design for a fermenter reaction vessel.

But the cited patent US 4,808,419 [D] is relied upon to demonstrate that fermenters for submerged or semi-solid fermentation of vegetable materials by microbial enzymatic hydrolysis including the use of koji preparation derived from *Aspergillus oryzae* are known in the art and commercially available (see abstract or Fig. 1 or col. 10, line 30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice the method of US 6,045,819 [A] in "a submerged culture fermenter-type reaction vessel" as intended the presently claimed invention with a reasonable expectation of success in producing hydrolyzed proteins with decreased amounts of reducing sugars because various fermenters including submerged culture fermenter-type reaction vessel are known in the prior art as demonstrated by US 4,808,419 [D], for example, and they are available for fermentation and hydrolysis of vegetable materials including koji fermentation. One of skill in the art is free to choose a fermenter suitable for koji fermentation which is known and/or available on a market. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims 7, 8, 14, 15 and 22-26 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,045,819 [A] and WO 95/28853 [N] in view of US 5,888,561 [C] and US 4,808,419 [D].

The claims 7, 8 and 22-26 as explained above. Claims 14 and 15 are further drawn to pre-treatment of vegetable protein material by steps of pulverizing, dispersing, removing air bubbles and sterilizing the vegetable protein material prior to fungal fermentation.

The cited references US 6,045,819 [A] and WO 95/28853 [N] are relied upon as explained above. They both teach methods for producing hydrolyzed vegetable protein material having substantially decreased amounts of reducing sugars by applying two temperature stage fermentation with koji mold fungal culture.

WO 95/28853 [N] is silent with regard to pre-treatment of vegetable material prior to fermentation such as pulverizing, dispersing, removing air bubbles and sterilizing the vegetable protein material. However, the cited US 6,045,819 [A] encompasses steps of pulverizing, dispersing, removing air bubbles and sterilizing the vegetable protein material prior to fungal fermentation as explained above. Thus, US 6,045,819 clearly teaches and suggests application of similar pre-treatment steps in the method for producing hydrolyzed protein material.

Further, the cited US 5,888,561 is relied upon to demonstrate that pre-treatment of vegetable material by pulverization and sterilization prior to koji mold fermentation is a conventional procedure (example 1) in the method for producing hydrolyzed proteins characterized by decreased amounts of reducing sugars (col. 1, line 63-66). In addition, the cited patent US 5,888,561 also discloses a step removing air bubbles from the pulverized and dispersed vegetable material prior to sterilization by teaching that soaked vegetable extrudates were subjected to vacuum before pasteurization (col. 3, line 48).

Further, the cited patent US 4,808,419 [D] is relied upon as explained above to demonstrate that fermenters for submerged or semi-solid fermentation of vegetable materials by microbial enzymatic hydrolysis including the use of koji preparation derived from *Aspergillus oryzae* are known in the art and commercially available (see abstract or Fig. 1 or col. 10, line 30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to subject the vegetable material to a pre-treatment prior to enzymatic fermentation in the methods of US 6,045,819 [A] or WO 95/28853 [N] as suggested by US 6,045,819 [A] with a reasonable expectation of success in producing hydrolyzed proteins because pre-treatment including pulverization, dispersion, removing of air bubbles and sterilization are conventional procedures in the methods for koji mold fermentations as evidenced by US 5,888,561. Further, with respect to pulverization step, it is considered to be a choice of experimental design to pulverize the vegetable material to various sizes including that of 300 μm or less as encompassed by the claimed method in the absence of evidence to the contrary.

Moreover, the instant application does not regard the importance of size being 300 μm or less and it teaches alternative use of particle sizes more than 300 μm (See specification page 11, par. 3). The comparative example in the applicants' specification is directed to the advantage of two temperature stage fermentation when compared to one temperature stage fermentation in a method for making hydrolyzed product with decreased amount of reducing sugars (see pages 25-27 and tables 1-2) rather than to criticality of a specific protocol of pre-treatment of vegetable material prior to koji fermentation. One of skill in the art is free to choose a fermenter suitable for koji fermentation which is known and/or available on a market {US 4,808,419 [D]}. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicants' arguments and Declaration filed 4/21/2003 have been fully considered but they are not persuasive for the reasons below.

With regard to the cited patent WO 95/28853 [N] {Muller et al.} applicants argue that it does not teach the use of a "submerged culture fermenter-type reaction vessel" (response page 5). However, since the differences between starting koji mold fungal cultures derived from either "submerged culture fermenter-type reaction vessel" as claimed or derived from a tray as in the

cited patent can not be reasonably or clearly delineated, the applicants' argument does not appear to have persuasive grounds. Thus, the fungal cultures which are made either in a tray or in a "submerged culture fermenter-type reaction vessel" are not at least functionally different because they are both suitable for enzymatic hydrolysis of vegetable material. Further, the present invention does not appear to utilize any specially designed fermenter neither for koji inoculum preparation nor for enzymatic hydrolysis step. Moreover, the presently claimed method does not require the use of a "submerged culture fermenter-type reaction vessel" in the step of enzymatic hydrolysis.

With regard to the method of US '819 (Takebe) applicants argue that one of skill in the art would not recognized the fermenter or "device" for enzymatic fermentation as a "submerged culture fermenter-type reaction vessel" (response page 6, par. 1). However, the present invention does not utilize a specially designed fermenter for koji inoculum preparation or for enzymatic hydrolysis step to support the instant argument and/or to point out the differences which might be intended. Thus, the "device" of the cited patent US '819 (Takebe), which is used for enzymatic fermentation in the presence of water or in aqueous medium wherein the method results in production of identical hydrolyzed protein lacking reducing sugars, is considered to be substantially similar at least in its effects to a "submerged culture fermenter-type reaction vessel" as claimed and as intended by applicants.

Applicants also argue that the cited patent US '819 (Takebe) discloses fluctuations of temperature during fermentation (response page 6, par. 2). However, the claimed invention

allows for the same changes within ranges of about 15-39°C or of about 25-38°C during first temperature stage fermentation with agitation and aeration as it is demonstrated in the process of the cited patent. The process as claimed does not require that the temperature be maintained at certain level. Thus, the temperature fluctuations are within the scope of the claimed invention. Moreover, the claimed method does not comprise the use of a "submerged culture fermenter-type reaction vessel" during the step of enzymatic hydrolysis.

The Applicant's arguments based on the Declaration are not persuasive because the results of the Declaration are confusing as to the significance of the differences in the method productivity indicated.

The applicants' argument drawn to the use of one microorganism (Declaration page 2, it. 7 or response page 8) is not found persuasive because the same fungal culture such as koji mold belonging to the species of *Aspergillus oryzae* is used in the methods of the cited references and in the applicants' invention as claimed and as disclosed.

. Further, Applicants appear to argue that the unexpected result such as preventing the final product from browning is due to a particular temperature shift during enzymatic hydrolysis. However, the prior art clearly teaches the use of the same temperature shift within the same temperature ranges. Moreover, the prior art teaches obtaining a hydrolyzed product with a "lighter" color than the brown color {WO 95/28853} and/or the prior art demonstrates the absence of reducing sugars at the end of enzymatic fermentation {US '819 (Takebe)}. Thus, the

final products of the cited references are prevented from "browning" within the meaning of the claimed invention.

Furthermore, the scope of the showing must commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim. The protocol of experiment disclosed in the Declaration (pages 3-4) encompasses the use of conditions which are not within the claimed invention, for example: amounts and contents of the starting vegetable material, particular conditions for pretreatment, the use of two different vegetable materials for making koji mold fungal culture and for making hydrolyzed protein, time intervals for two stage fermentation and others. In addition, it remains uncertain as claimed and as argued what is measured to determine the claimed degree of "completion" of enzymatic reaction. For example: some of the arguments are drawn to the glutamic acid amounts (response page 7, last par.), however the claimed invention does not encompass glutamic acid or measuring of glutamic acid concentration. It is uncertain what amounts of reducing sugars are within the starting vegetable materials to consider "a ratio" which is claimed and/or to obtain the product with less than 5% of reducing sugar.

Applicants appear to argue the idea or a goal of "maintaining hydrolysis speed" (response page 10, par. 1) but claims are not limited to any speed or to time intervals. Moreover, the hydrolysis speed or time for hydrolysis would be reasonably expected to depend on amounts and specific characteristics of materials involved in the process.

The results of the Figure B in the Declaration copy can not be read.

Therefore, the results of the Declaration are confusing as to the significance of the differences in the method productivity as argued.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

Art Unit 1651

July 10, 2003.

IRENE MARY
PRIMARY EXAMINER